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ONE HUNDRED TENTH CONGRESS

## U.S. House of Representatives Committee on Energy and Commerce Washington, DC 20515-6115

JOHN D. DINGELL, MICHIGAN CHAIRMAN

February 27, 2007

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Ms. Sharon Price Hill
Chief Executive Officer and
Chairman of the Board
Copernicus Group IRB
118 MacKenan Drive, Suite 400
Cary, North Carolina 27511

Via FAX (919-465-4311)

Dear Ms. Hill:

Pursuant to Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations are conducting an inquiry into the adequacy of the efforts of the U.S. Food and Drug Administration (FDA) to protect the American public from excessive risks from prescription drugs. As part of that investigation, we are examining the circumstances surrounding the Sanofi-Aventis antibiotic Ketek.

That drug was, in part, the subject of our hearing on February 13, 2007. During the course of that hearing certain questions arose regarding the proper protection of human subjects in a "usual care" clinical trial referred to as TREAT or study 3014. Your firm was identified as the for-profit Institutional Review Board (IRB) contracted by Aventis (now Sanofi-Aventis) to monitor the human subjects in the study.

In order to understand the conduct of that trial, we require certain information. We request that you provide us with all records relating to:

- 1. The contract between Copernicus and Aventis relating to study 3014.
- 2. The development of the protocol and the informed consent forms relating to study 3014.

- 3. Adverse events reported to Copernicus relating to subjects in study 3014 regardless of the source of those reports.
- 4. Adverse events that Copernicus reported to the FDA relating to subjects in study 3014.
- 5. Financial arrangements between Copernicus and Aventis relating to study 3014.
- 6. The names and contact information for all Copernicus employees assigned to study 3014.

All the requested records should please be delivered to the Committee on Energy and Commerce offices at Room 316 Ford House Office Building by no later than the close of business on Friday, March 9, 2007. Please note that the words "records" and "relating to" should be interpreted as defined on the attachment to this letter. Should you have any questions regarding this request, please contact David Nelson of the Committee Majority staff at (202) 225-2927 or Alan Slobodin of the Committee Minority staff at (202) 225-3641.

Sincerely,

John D. Dingell

Chairman

Committee on Energy and Commerce

Joe Barton

Ranking Member

Committee on Energy and Commerce

Bart Stupak

Chairman

Subcommittee on Oversight

and Investigations

Ed Whitfield

Ranking Member

Subcommittee on Oversight

and Investigations

Attachment

## **ATTACHMENT**

- The term "records" is to be construed in the broadest sense and shall mean any written or 1. graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intradepartmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
- 2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.